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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GRUN, JAMES LESLIE

ART UNIT	PAPER NUMBER
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1641

NOTIFICATION DATE	DELIVERY MODE
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12/21/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/593,372	Applicant(s) KETELSLEGGERS ET AL.	
	Examiner JAMES L. GRUN	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 99-107 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 99-107 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09 November 2010 has been entered. Claims 99-107 remain in the case.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 103 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 103, "the" method of claim 1 lacks antecedent basis and the claim depends from a canceled claim; it is believed --99-- was intended.

Applicant's arguments filed 09 November 2010 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 99-107 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Selvais et al. (J. Cardiac Failure 6: 201, 2000), Hülsmann et al. (J. Am. Coll. Cardiol. 32: 1695, 1998), Rousseau et al. (Circulation 108 (17 Suppl.): IV-556, 2003), Berger et al. (J. Heart Lung Transplant. 22: 1037, 2003), and Sabatine et al. (Circulation 105: 1760, 2002) for reasons of record in the prior rejection of the similar subject matter of these claims.

Applicant's arguments filed 09 November 2010 have been fully considered but they are not deemed to be persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this regard, applicant urges that none of the references teach determination of big endothelin and full-length N-proANP. This is not found persuasive for the reasons of record, particularly in view of the combined teachings of Selvais et al. (2000), Rousseau et al., Hülsmann et al., and Berger et al. Applicant

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further urges that Selvais et al. (2000) do not specifically exemplify determinations of big endothelin. This is not found persuasive for the reasons of record in view of the direct suggestions in Selvais et al. (2000) to do so and in view of the teachings of Rousseau et al., Hülsmann et al., and Berger et al. Applicant further urges that Rousseau et al. do not teach determination of multiple markers. This is not found persuasive for the reasons of record, particularly in view of the teachings of Selvais et al. (2000), Hülsmann et al., Berger et al., and Sabatine et al. Applicant further urges that Hülsmann et al. or Berger et al. do not teach determination of two markers together. This is not found persuasive for the reasons of record.

Applicant's arguments regarding the use of the assay for predictions in mild congestive heart failure patients were not found persuasive because applicant is arguing limitations not found in the instantly rejected claims and not commensurate in scope with the invention as instantly claimed.

Notwithstanding applicant's assertions to the contrary, one of ordinary skill in the art would have appreciated that markers shown to be independent in multivariate analysis each provide unique complementary prognostic information that can be combined to provide an improved prognosis as clearly taught in the references such as Selvais et al. (2000), Hülsmann et al., Berger et al., and/or Sabatine et al. Moreover, the examiner did not suggest, as argued in applicant's response, directly importing big endothelin-1 (ET-1) into the reference of Selvais et al. (2000) as a substitute for the determinations of endothelin-1 (ET-1) therein, because, for the reasons of record, the combined teachings of the references suggest that the determination of big endothelin and N-proANP should be performed because, inter alia, big endothelin is more stable and easier to measure than ET-1 as taught in Selvais et al. (2000), big ET-1 and ET-1 were

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strong independent predictors of 5 year survival in patients with severe congestive heart failure (NYHA classes III-IV) as taught in Rousseau et al., and determinations of big endothelin and N-proANP or ANP were best for predicting survival in all congestive heart failure patients as taught in Berger et al. or Hülsmann et al. As set forth, one of ordinary skill in the art would have been motivated to use the successful methods in combination in a method of prognosis prediction because determinations of these analytes had been taught individually or in the same combinations as instantly claimed or in different combinations by the relied upon prior art to be effective in the prediction of death in congestive heart failure patients and it would have been obvious to predict survival with multiple markers because the idea of doing so would have followed logically from their having been individually taught, as well as in the same or in other combinations, in the relied upon prior art to be useful for the same purpose, and, in particular, it would have been obvious to combine the determinations and individual cut-offs for each analyte in view of the direct suggestions in Selvais et al. (2000) to do so as well as in view of Sabatine et al. for the benefits taught therein.

The declaration of Dr. Gerhard Hawa under 37 CFR 1.132 filed 09 November 2010 is insufficient to overcome the rejection of claims 99-107 under 35 U.S.C. § 103(a) over the combined teachings of Selvais et al. (J. Cardiac Failure 6: 201, 2000), Hülsmann et al. (J. Am. Coll. Cardiol. 32: 1695, 1998), Rousseau et al. (Circulation 108 (17 Suppl.): IV-556, 2003), Berger et al. (J. Heart Lung Transplant. 22: 1037, 2003), and Sabatine et al. (Circulation 105: 1760, 2002) as set forth in the last Office action because:

It refers only to the system described in the above referenced application and not to the individual claims of the application. This is particularly evidenced by the focus of the

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declaration on mild congestive heart failure when the claims are limited to severe congestive heart failure. As such the declaration does not show that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716. Moreover, the examiner did not suggest, as argued in the declaration, directly importing big endothelin-1 (ET-1) into the reference of Selvais et al. (2000) as a substitute for the determinations of endothelin-1 (ET-1) therein, because, for the reasons of record, the combined teachings of the references suggest that the determination of big endothelin and N-proANP should be performed because, inter alia, big endothelin is more stable and easier to measure than ET-1 as taught in Selvais et al. (2000), big ET-1 and ET-1 were strong independent predictors of 5 year survival in patients with severe congestive heart failure (NYHA classes III-IV) as taught in Rousseau et al., and determinations of big endothelin and N-proANP or ANP were best for predicting survival in all congestive heart failure patients as taught in Berger et al. or Hülsmann et al.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness. The rejection is maintained.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, SPE, can be contacted at (571) 272-0806.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J. L. G./

James L. Grun, Ph.D.

Examiner, Art Unit 1641

December 16, 2010

/Shafiqul Haq/

Primary Examiner, Art Unit 1641